REMARKS

Entry of the foregoing and further and favorable consideration of the subject application in light of the following amendments and remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

I. CLAIM STATUS & CLAIM AMENDMENTS

As correctly indicated in the Office Action Summary, claims 10-12 and 15 were pending in this application when last examined.

Claims 10 and 11 have been amended to recite "An isolated glycoprotein antigen" as suggested by the Examiner. Support for the amendment to claims 10 and 11 can be found in the Specification, at least, at page 22, line 17 to page 23, line 7. Thus, no prohibited new matter has been added by this amendment.

II. CLAIM OBJECTIONS

Claim 11 is objected to as allegedly failing to further limit claim 10. The Examiner has stated that dependent claim 11 recites characteristics of the claimed antigen which are inherent in independent claim 10. See April 9, 2003 Official Action, page 3.

Applicants respectfully traverse this rejection. Nonetheless, for the sole purpose of expecting prosecution and not to acquiesce to the Examiner's rejection, Applicants have amended claim 11 such that it is an independent claim. Therefore, the amendment obviates

this rejection. Accordingly, Applicants respectfully request the withdrawal of this objection.

III. REJECTIONS

A. Non-Statutory Subject Matter

Claims 10 and 11 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. See April 9, 2003 Official Action; page 2.

The claims have been amended to recite "An isolated glycoprotein antigen. . . " as suggested by the Examiner. Since the amendment obviates the rejection, Applicants respectfully request the withdrawal of this rejection.

B. Double Patenting Rejection

Claim 11 has been rejected under 35 U.S.C. § 101 as allegedly claiming the same invention as that of claim 4 of U.S. Patent No. 6,015,680 (hereinafter "'680 patent"). See April 9, 2003 Official Action, page 3. Applicants respectfully traverse this rejection for at least the following reasons.

Statutory double patenting does not apply.

35 U.S.C. § 101 prevents two patents from issuing on the "same invention." The same invention means **identical** subject matter. In determining whether a basis for a statutory double patenting rejection exists, the question to be asked is whether the **same** invention is being claimed twice. Miller v. Eagle Mfg. Co., 151 U.S. 186 (1984); In re

Vogel, 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970); M.P.E.P. § 804, II, A. A reliable test for double patenting under 35 U.S.C. § 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent. In other words, if an embodiment of the invention that falls within the scope of one claim, but not the other, than statutory double patenting does not exist. In re Vogel, 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970).

In the instant case, claim 11 of the instant invention is directed to an isolated glycoprotein antigen. Claim 4 of the '680 patent, on the other hand, is directed to an immunoassay method of diagnosis. The method of claim 4 the '680 patent contains embodiments, such as the various method steps, which are not present in the product composition of claim 11 of the instant invention. Accordingly, statutory double patenting does not apply in this situation.

During a brief informal telephonic discussion with Examiner Canella held on July 29, 2003, Applicants discussed the applicability of this rejection to claim 11. At this time, Examiner Canella indicated that the rejection contained an inadvertent typographical error in that the rejection should be over claim 12, not claim 11.

However, to the extent the Examiner intended for this rejection to be over claim 12, instead of claim 11 of the instant invention, Applicants submit that statutory double patenting does not apply in this situation. Claim 12 of the instant invention is directed to an immunoassay using a monoclonal antibody or a fragment of a glycoprotein antigen. Claim 4 of the '680 patent is directed to an immunoassay using only a monoclonal

antibody. The claims in the instant invention contain elements not present in the claims in the '680 patent. Consequently, the claims in the instant invention can not be said to claim **identical** subject matter to the claims in the '680 patent. Thus, for at least this reason, statutory double patenting does not apply to claim 12.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this Amendment and Reply or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: September 9, 2003

By: _____
Jay F. Williams
Registration No. 48,036

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620